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510(k) SUMMARY

Andrew Technologies' Phaser Lipoplasty System (K092066)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Contact Person: Luis Davila
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APR 12 2010

Date Prepared: April 12, 2010

Name of Device and Name/Address of Sponsor:

Phaser™ Lipoplasty System

Andrew Technologies, LLC
3 South Haddon Avenue, Suite 3
Haddonfield, NJ 008033

Common or Usual Name: Suction Lipoplasty System

Classification Name: Suction Lipoplasty System, Class II, 21 C.F.R. § 878.5040 (MUU)

Predicate Devices

1. Alcon Laboratories, Cataract Liquefracture Device (K980292)
2. Misonix Inc., Lysonix 2000/3000 Ultrasonic Surgical Aspiration Systems (K041058)
3. Soring GmbH Medizintechnik, Sonoca-Lipo (K052183)
4. Byron Medical, PSI-Tec Liposuction Aspirator (K981215)
5. Byron Medical , PSI-Tec Syringe Infusion Pump (K040149)
6. Byron Medical, Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles (K981172)
7. HK Surgical Inc., HK Liposuction Aspirator III (K032802)

Intended Use / Indications for Use

The Phaser Lipoplasty System is intended to be used for liquefaction and aspiration of localized subcutaneous fatty deposits for the purpose of aesthetic body contouring.

The Phaser Lipoplasty System is indicated for use in aesthetic body contouring.

Technological Characteristics

The Phaser Lipoplasty System is a surgical liposuction device that utilizes pressurized, heated and pulsed saline streams ("the Phaser stream") in conjunction with a specialized

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cannula to transition adipose tissue from a solid state to a liquid or gel state so as to facilitate its removal from the body. The physician can employ standard surgical liposuction techniques when using the device, the low pressure and temperature allow adipose tissue removal without burning or otherwise damaging non-target tissues within the surgical field.

Performance Data

The company conducted in-vivo testing in a porcine model to assess the safety and performance of the device and the heat generated at the entrance/puncture site, comparing these results to concurrent testing performed with suction assisted lipoplasty (SAL). Temperature readings were taken from worst case locations on the skin surface and on the highest temperature region of the cannula. In addition, tissue was examined histologically to assess potential thermal damage. The data gathered in this study confirms that there is no thermal damage association with the use of the Phaser, with the impact on the Phaser test animals' skin directly comparable to the effects seen with SAL. Specifically, average skin temperatures with the Phaser ranged from 31.4 to 35.8°C as compared to 26.2 to 31.1°C for SAL. Average Phaser cannula temperatures ranged from 36.7 to 40.2°C, with corresponding SAL cannula temperatures of 28.5 to 33.8°C. Importantly, no histological evidence of thermal damage was seen with either the Phaser or SAL.

A simulated use study to address the use environment and the device user interface was also performed. The study evaluated human factor considerations, including the device's use environment, user capabilities, and the product's user interface. These evaluations demonstrated that the device performed and functioned as intended.

Substantial Equivalence

The Phaser Lipoplasty System has the same intended uses and similar indications, technological characteristics, and principles of operation as the following predicate devices: the Misonix Inc. Lysonix 2000/3000 Ultrasonic System (K041058); the Soring GmbH, Sonoca Lipo (K052183) ("Sonoca-Lipo"); the Alcon Cataract Liquefracture Device (K980292); the PSI-Tec Peristaltic Infiltration Pump, Byron Medical Inc. (K040149); the Byron Medical Inc. PSI-Tec Liposuction Aspirator (K981215); the Byron Medical Inc. Byron Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles (K981172); and the HK Surgical Inc., HK Liposuction Aspirator III (K032802). The minor technological differences between the Phaser Lipoplasty System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Phaser Lipoplasty System has comparable performance and safety as compared to the Lysonix 2000/3000, Sonoca-Lipo and the AquaLase. Thus, the Phaser Lipoplasty System is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Andrew Technologies, LLC
% Hogan & Hartson LLP
Mr. Luis Davila
555 13th Street, Northwest
Washington, District of Columbia 20004

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Re: K092066
Trade Name: Phaser™ Lipoplasty System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: April 9, 2010
Received: April 9, 2010

Dear Mr. Davila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K092066

Device Name: Phaser™ Lipoplasty System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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